

# EXHIBIT D

### Materials Considered

- ECRI Institute. Forced-air warming and surgical site infections. *Health Devices*. 2013; 122-125
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- Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection.  
<http://www.msis-na.org/wp-content/themes/msis-temp/pdf/ism-periprosthetic-joint-information.pdf>. Accessed 5/19/17
- UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA Safety Communication

<b>Bair Huggler</b>
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Dr. Wenzel Science Day Presentation, May 19, 2016

Expert Report of Dr. Michael J. Stonnington

Expert Report of William Jarvis

## Materials Considered

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**Bair Hugger**

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✓  Memarzadeh F. Active warming systems to maintain perioperative normothermia in hip replacement surgery. *J Hosp Infect.* 2010; 1-2


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UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA Safety CommunicationAevis  
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Expert Report of Dr. Michael J. Stonnington

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8/5/2017

Surgical complications - details

# Medicare.gov | Hospital Compare

The Official U.S. Government Site for Medicare

## Surgical complications - details

Data collection periods for all measures can be found [here](#).

### ▼ Table 1 of 3 Rate of complications for hip/knee replacement patients

. They do not include people in Medicare Advantage (like an HMO or PPO) plans or people who do not have Medicare.

The results show differences in complication rates for Medicare beneficiaries after hip and/or knee replacement. The results account for how sick patients were when they were hospitalized.

National complication rate for hip/knee replacement patients was 2.8%<sup>20</sup>

Hospital name	Better than the national rate	No different than the national rate	Worse than the national rate
NEWTON-WELLESLEY HOSPITAL		X	

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Surgical complications - details

The table below shows the number of hospitals in each complication rate category across the nation and the state.

**Out of 3457 hospitals in the United States →**      **66** hospitals were better than national rate      **2699** hospitals were no different than national rate      **38** hospitals were worse than national rate

**654** hospitals did not have enough cases to reliably tell how well they are performing

**Out of 58 hospitals in Massachusetts →**      **1** hospital was better than national rate      **53** hospitals were no different than national rate      **1** hospital was worse than national rate

**3** hospitals in Massachusetts did not have enough cases to reliably tell how well they are performing

For more information, click on the links below:

- [How are hospital complication rates after hip/knee replacement calculated?](#)
- [Get the current data period](#)

### ▼ **Table 2 of 3 Serious complications**

The table below compares serious complications for selected hospitals and the nation among select patients. These comparisons take into account the age of the patient, how sick the patients were before they were admitted to the hospital, if they were transferred from another hospital, and differences that might be due to chance.

They do not include people in Medicare Advantage (like an HMO or PPO) plans or people who do not have Medicare.

National composite value for serious complications = 0.90<sup>20</sup>

Hospital name	Better than the national value (PSI 90 Composite value is lower than the national composite value)	No different than the national value (PSI 90 Composite value is about the same as the national composite value)	Worse than the national value (PSI 90 Composite value is higher than the national composite value)
<b>NEWTON-WELLESLEY HOSPITAL</b>		<b>X</b>	

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Surgical complications - details

<b>Out of 3411 hospitals in the United States →</b>	<b>104 hospitals were better than national rate</b>	<b>3112 hospitals were no different than national rate</b>	<b>195 hospitals were worse than national rate</b>
<b>Out of 61 hospitals in Massachusetts →</b>	<b>2 hospitals were better than national rate</b>	<b>56 hospitals were no different than national rate</b>	<b>3 hospitals were worse than national rate</b>

▼ **Table 3 of 3 Deaths among patients with serious treatable complications after surgery**

They do not include people in Medicare Advantage (like an HMO or PPO) plans or people who do not have Medicare.

The table below compares in-hospital deaths among patients with serious treatable complications after surgery for selected hospitals and the national rates among patients with serious treatable complications after surgery. These comparisons take into account the age of the patient, how sick the patients were before they were admitted to the hospital, if they were transferred from another hospital, and differences in mortality rates that might be due to chance.

They do not include people in Medicare Advantage (like an HMO or PPO) plans or people who do not have Medicare.

National rate in-hospital deaths among patients with serious treatable complications after surgery = 136.48<sup>20</sup> per 1,000 patient discharges.

<b>Hospital name</b>	<b>Better than the national rate (smoothed rate is lower than the national rate)</b>	<b>No different than the national rate (smoothed rate is about the same as the national rate)</b>	<b>Worse than the national rate (smoothed rate is higher than the national rate)</b>
<b>NEWTON-WELLESLEY HOSPITAL</b>		<b>X</b>	

8/5/2017

Surgical complications - details

**Out of 2876 hospitals in the United States →****26 hospitals were better than national rate****1791 hospitals were no different than national rate****41 hospitals were worse than national rate****1018 hospitals did not have enough cases to reliably tell how well they are performing****Out of 57 hospitals in Massachusetts →****0 hospitals were better than national rate****40 hospitals were no different than national rate****0 hospitals were worse than national rate****17 hospitals in Massachusetts did not have enough cases to reliably tell how well they are performing**If footnotes appear in the table, hover over the number to get more details. [View more footnote details.](#)

## Footnotes

**Footnote number****Footnote as displayed on Hospital Compare****1**

The number of cases/patients is too few to report.

**2**

Data submitted were based on a sample of cases/patients.

**3**

Results are based on a shorter time period than required.

**4**

Data suppressed by CMS for one or more quarters.

**5**

Results are not available for this reporting period.

**6**

Fewer than 100 patients completed the HCAHPS survey. Use these scores with caution, as the number of surveys may be too low to reliably assess hospital performance.

**7**

No cases met the criteria for this measure.

**8**

The lower limit of the confidence interval cannot be calculated if the number of observed infections equals zero.

**9**

No data are available from the state/territory for this reporting period.

**10**

Very few patients were eligible for the HCAHPS survey. The scores shown reflect fewer than 50 completed surveys. Use these scores with caution, as the number of surveys may be too low to reliably assess hospital performance.

**11**

There were discrepancies in the data collection process.

**12**

This measure does not apply to this hospital for this reporting period.

**13**

Results cannot be calculated for this reporting period.

**14**

The results for this state are combined with nearby states to protect confidentiality.

**15**

The number of cases/patients is too few to report a star rating.

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Surgical complications - details

<b>Footnote number</b>	<b>Footnote as displayed on Hospital Compare</b>
<b>16</b>	There are too few measures or measure groups reported to calculate a star rating or measure group score.
<b>17</b>	This hospital's star rating only includes data reported on inpatient services.
<b>18</b>	This result is not based on performance data; the hospital did not submit data and did not submit a waiver
<b>19</b>	Data are shown only for hospitals that participate in the Inpatient Quality Reporting (IQR) and Outpatient Quality Reporting (OQR) programs.
<b>20</b>	State and national averages do not include VHA hospital data.
<b>21</b>	Patient survey results for VHA hospitals do not represent official HCAHPS results and are not included in state and national averages.
<b>22</b>	Star ratings are not calculated for VHA hospitals.
<b>*</b>	For Maryland hospitals, no data are available to calculate a PSI 90 measure result; therefore, no performance decile or points are assigned for Domain 1 and the Total HAC score is dependent on the Domain 2 score.
<b>**</b>	This value was calculated using data reported by the hospital in compliance with the requirements outlined for this program and does not take into account information that became available at a later date.

# Compliance with Surgical Care Improvement Project for Body Temperature Management (SCIP Inf-10) Is Associated with Improved Clinical Outcomes

Andrew V. Scott, B.S., Jerry L. Stonemetz, M.D., Jack O. Wasey, B.M., B.Ch., Daniel J. Johnson, B.S., Richard J. Rivers, M.D., Colleen G. Koch, M.D., M.S., Steven M. Frank, M.D.

## ABSTRACT

**Background:** In an effort to measure and improve the quality of perioperative care, the Surgical Care Improvement Project (SCIP) was introduced in 2003. The SCIP guidelines are evidence-based process measures designed to reduce preventable morbidity, but it remains to be determined whether SCIP-measure compliance is associated with improved outcomes.

**Methods:** The authors retrospectively analyzed the electronic medical record data from 45,304 inpatients at a single institution to assess whether compliance with SCIP Inf-10 (body temperature management) was associated with a reduced incidence of morbidity and mortality. The primary outcomes were hospital-acquired infection and ischemic cardiovascular events. Secondary outcomes were mortality and hospital length of stay.

**Results:** Body temperature on admission to the postoperative care unit was higher in the SCIP-compliant group ( $36.6^{\circ} \pm 0.5^{\circ}\text{C}$ ;  $n = 44,064$ ) compared with the SCIP-noncompliant group ( $35.5^{\circ} \pm 0.5^{\circ}\text{C}$ ;  $n = 1,240$ ) ( $P < 0.0001$ ). SCIP compliance was associated with improved outcomes in both nonadjusted and risk-adjusted analyses. SCIP compliance was associated with a reduced incidence of hospital-acquired infection (3,312 [7.5%] *vs.* 160 [12.9%] events; risk-adjusted odds ratio [OR], 0.68; 95% CI, 0.54 to 0.85), ischemic cardiovascular events (602 [1.4%] *vs.* 38 [3.1%] events; risk-adjusted OR, 0.60; 95% CI, 0.41 to 0.92), and mortality (617 [1.4%] *vs.* 60 [4.8%] events; risk-adjusted OR, 0.41; 95% CI, 0.29 to 0.58). Median (interquartile range) hospital length of stay was also decreased: 4 (2 to 8) *versus* 5 (2 to 14) days;  $P < 0.0001$ .

**Conclusion:** Compliance with SCIP Inf-10 body temperature management guidelines during surgery is associated with improved clinical outcomes and can be used as a quality measure. (ANESTHESIOLOGY 2015; 123:00-00)

THE optimal methods for measuring and reporting quality of surgical care are controversial.<sup>1-3</sup> In the past decade, quality assessment has been based predominantly on process measures rather than outcome measures, because these are easy to report and may not require risk adjustment.<sup>4,5</sup> The Surgical Care Improvement Project (SCIP)<sup>6</sup> was instituted in 2003 in an effort to improve the quality of perioperative care and reduce preventable adverse outcomes. The SCIP National Quality Core Measures are evidence-based clinical care guidelines that are audited and reported to a national database and have been used as a quality measure to compare hospitals. Such a database, called the Hospital Compare Web site,<sup>7</sup> is made publicly available to consumers by the Centers for Medicare and Medicaid Services. What remains to be determined is whether SCIP-measure compliance correlates with reduced morbidity or mortality. In fact, numerous prior studies have reported no difference in morbid outcomes in relation to SCIP-measure compliance,<sup>8-14</sup> calling into question the use of process measures rather than outcome measures for quality assessment.

Initially, the SCIP measures were created to reduce the incidence of hospital-acquired infection, deep venous thrombosis, pulmonary embolus, and ischemic cardiovascular

## What We Already Know about This Topic

- There is limited evidence that compliance with process measures such as maintenance of normothermia reduces postoperative morbidity
- The hypothesis that compliance with the Surgical Care Improvement Project maintenance of normothermia measure reduces postoperative infection and cardiovascular ischemia was analyzed retrospectively

## What This Article Tells Us That Is New

- Data from 45,304 noncardiac surgical patients at a single academic medical center found that 1,240 were noncompliant (body temperature  $<36^{\circ}\text{C}$  or no use of active warming)
- Noncompliant patients had an increased risk of infection, ischemic events, and mortality, supporting maintenance of normothermia as a useful perioperative quality measure

events. Of these morbid outcomes, infection is most common and has been associated with substantially increased cost, length of stay, and even mortality.<sup>15</sup> Currently, there are eight SCIP measures intended to reduce hospital-acquired infection, including SCIP Inf-10, which relates to the maintenance of normothermia in surgical patients. SCIP Inf-10 is

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based on the findings of a randomized clinical trial by Kurz *et al.*,<sup>16</sup> published in 1996, wherein the investigators demonstrated that active warming of patients undergoing colorectal surgery was associated with a threefold reduction in the incidence of wound infections. Another reason for actively warming patients is that residual postoperative hypothermia has been associated with an increased incidence of ischemic cardiovascular events.<sup>17</sup> Despite the evidence-based nature of the SCIP Inf-10 body temperature management guideline, little evidence shows that compliance with this process measure is helpful in reducing perioperative morbidity.

The SCIP Inf-10 measure states that patients who undergo surgical procedures that last greater than or equal to 60 min should either (1) be actively warmed or (2) have a body temperature greater than or equal to 36°C within 30 min immediately before or 15 min after anesthesia end time.<sup>18</sup> In this study, we tested the hypothesis that SCIP Inf-10 compliance is associated with a decreased incidence of hospital-acquired infections and a reduced incidence of ischemic cardiovascular events, when compared with surgical cases that were SCIP Inf-10 noncompliant. We also sought to determine whether mortality and length of stay were reduced in SCIP-compliant patients.

## Materials and Methods

After receiving approval from the institutional review board at the Johns Hopkins Medical Institutions (Baltimore, Maryland), we acquired electronic anesthesia records from the anesthesia information management system (Metavision®; iMDSoft, USA) for 46,683 inpatients who underwent noncardiac surgery between January 2010, and June 2014. Cardiac surgeries were not included because of the unique thermal perturbations with these surgeries. The anesthesia database includes information regarding use of active patient warming measures and body temperature data recorded in the operating room and on admission to the postanesthesia care unit (PACU) or intensive care unit (ICU) after surgery. These records were merged with a second database derived from the hospital's billing records (Datamart, Microsoft SQL server database software, USA), and a third database made available through a Web-based intelligence portal (IMPACT Online; Haemonetics Corp., USA). Our use of these databases and the quality control methods used have been described previously.<sup>19,20</sup> The Datamart database includes up to 29 preadmission comorbidities for each patient, and the IMPACT Online database includes hospital-acquired morbid events that are determined by *International Classification of Diseases*, ninth Revision (ICD-9) codes on discharge. Also included is the Charlson comorbidity index score derived from the preadmission comorbidities,<sup>21</sup> which we used in the risk-adjusted model described in Outcome Assessment and Statistical Analysis. After merging these databases, we excluded 1,379 patients who had surgical procedures that were less than 60 min in duration because these patients are exempt from the SCIP Inf-10 guideline for body temperature management. Thus, 45,304 patients were included in the analysis.

Intraoperative temperature measurements were taken according to the preference of the anesthesia team. At our institution, temperatures are typically measured by placing a thermistor probe (YSI, USA) in the oropharynx, nasopharynx, or proximal esophagus. Our institution does not use the "esophageal stethoscope" temperature probes that reach the distal esophagus. In 9,342 patients, the intraoperative temperature during the last 30 min of surgery (end of surgery) was not available. Either the probe was removed before the end of case (in 5,225 cases) or the temperature probe was removed from the patient and exposed to ambient temperature (in 4,117 cases). After surgery, the body temperature of each patient was measured on admission to the PACU or ICU with a temporal artery infrared thermometer (Exergen TAT-5000, USA), as it is the routine practice by the nursing staff.

Regarding the PACU/ICU admission temperature, 1,387 patients had missing measurements. All missing temperatures were treated as missing data, just as they would be when determining SCIP compliance according to the actual SCIP Inf-10 guideline. Only 96 patients (0.2%) were missing both end of surgery and PACU/ICU admission temperatures and thus were only defined as SCIP compliant if active warming was utilized.

Active warming measures at our institution typically include the forced-air method, with either an upper or lower body cover, or occasionally both upper and lower covers. Rarely, a circulating water mattress is used. All these methods are recorded in the electronic records that we used in the analysis to define active warming. Intravenous fluid warming alone was not defined as active warming.

Two groups were created based on the SCIP Inf-10 guideline, which we designated to be the "SCIP compliant" and "SCIP noncompliant" groups. If the highest of the two temperatures measured during (1) the last 30 min of surgery and (2) the first 15 min of postoperative care was greater than or equal to 36°C, or active patient warming was utilized, then the patient was deemed to be in the SCIP-compliant group. All other patients were deemed to be SCIP noncompliant.

Baseline characteristics in the two groups were compared. The primary outcomes were morbid events during the hospital stay, which are defined as (1) hospital-acquired infections and (2) ischemic cardiovascular events. Infections included postoperative wound infections, drug-resistant infections, sepsis, and *Clostridium difficile* infections. Ischemic cardiovascular events included myocardial infarction, cerebral vascular accident, and transient ischemic attack. The exact ICD-9 codes used to define each of these outcomes are shown in the appendix. Secondary outcomes included mortality during the hospital stay and hospital length of stay.

## Outcome Assessment and Statistical Analysis

The two groups were compared by using two-tailed Student *t* tests for continuous variables, chi-square tests for dichotomous variables, and the Mann-Whitney *U* test for nonparametric analyses (comparing medians and ordinal data). We

## PERIOPERATIVE MEDICINE

analyzed the relationship between SCIP Inf-10 compliance and clinical outcomes in both an unadjusted and a risk-adjusted fashion, using univariable and multivariable logistic regressions, respectively; the odds ratios (ORs) and 95% CIs are reported.

In the multivariable models, we included the design variable of the study (SCIP Inf-10 compliance) and those variables from table 1 (baseline patient characteristics) that occurred with different frequency between groups ( $P < 0.05$ ). To adjust for potential confounders, a propensity score was calculated from a logistic regression as the probability of being in the SCIP-noncompliant group, taking into account each of the baseline clinical characteristics in table 1. This propensity score was then forced in the logistic model. In addition, we included the calendar year of the surgery, duration of surgery, and receipt of an intraoperative blood transfusion, because these were considered potential confounding variables. The reported risk-adjusted ORs are from the multivariable logistic regression model with all covariates included.

Two additional multivariable models were constructed to determine (1) the independent association between active warming and outcomes and (2) the independent association between any body temperature greater than or equal to 36°C and outcomes. These models included the same methods described in the previous paragraph, except that the two components that comprise SCIP compliance: (1) use of active warming measures and (2) any temperature greater than or equal to 36°C, were substituted for “SCIP compliance” as independent variables in the model. To avoid the

likelihood of a type 1 error, a Bonferroni *post hoc* correction was used in both univariable and multivariable analyses of composite outcomes.

Continuous variables that were normally distributed are reported as mean  $\pm$  SD; those that were not normally distributed, as well as ordinal variables, are reported as median and interquartile range.  $P$  value less than 0.05 was used to define significance. Analyses were generated using JMP version 9.0.3 (SAS Institutes, Inc., USA), and R version 3.1.2 (<http://www.r-project.org>, accessed March 17, 2015).

## Results

The SCIP-compliant and SCIP-noncompliant groups were compared for preoperative patient characteristics and pre-hospital admission comorbidities (table 1). The two groups were comparable for age; gender; the prevalence of diabetes, liver disease, and human immunodeficiency virus disease; presence of tumor; anemia; alcohol or drug abuse; and psychiatric conditions. The SCIP-noncompliant group had a greater incidence of congestive heart failure, valvular cardiac disease, peripheral vascular disease, hypertension, pulmonary disease, and renal insufficiency/failure. The SCIP-compliant group had a greater incidence of metastatic disease and obesity. The incidence of SCIP-noncompliance decreased over the 4-yr time period: year 2010, 3.7%; 2011, 3.0%; 2012, 2.1%; 2013, 1.8% ( $P \leq 0.0001$ ). The distribution of patients in each group according to the surgical specialty service that performed the procedure is compared in table 2. The SCIP-compliant group had a greater percentage of general, spine, and plastic surgery cases than did the noncompliant group,

Table 1. Patient Characteristics

	SCIP Compliant (n = 44,064), No. (%)	SCIP Noncompliant (n = 1,240), No. (%)	P Value
Age (yr)	44 $\pm$ 24	44 $\pm$ 27	0.71
Gender (% male)	23,029 (52.3)	668 (53.9)	0.26
Charlson score, median (IQR)	1 (0–2)	1 (0–3)	0.0009
Comorbidities			
Congestive heart failure	1,236 (2.8)	68 (5.5)	<0.0001
Valvular cardiac disease	1,901 (4.3)	74 (6.0)	0.005
Peripheral vascular disease	1,684 (3.8)	116 (9.4)	<0.0001
Hypertension	12,758 (29.0)	396 (31.9)	0.023
Pulmonary	5,435 (12.3)	206 (16.6)	<0.0001
DM	4,484 (10.2)	139 (11.2)	0.24
Renal	2,562 (5.8)	102 (8.2)	0.0004
Liver	1,348 (3.1)	46 (3.7)	0.19
HIV	271 (0.6)	13 (1.1)	0.057
Metastatic disease	4,483 (10.2)	99 (8.0)	0.012
Tumor	10,198 (23.1)	271 (21.9)	0.29
Obesity	4,539 (10.3)	104 (8.4)	0.028
Anemia	4,275 (9.7)	122 (9.8)	0.87
Alcohol abuse	781 (1.8)	16 (1.3)	0.2
Drug abuse	789 (1.8)	16 (1.3)	0.19
Psychoses	852 (1.9)	25 (2.0)	0.84
Depression	2,598 (5.9)	59 (4.8)	0.093

DM = diabetes mellitus; HIV = human immune deficiency virus; IQR = interquartile range; SCIP = Surgical Care Improvement Project.

Table 2. Surgical Specialty Services

	SCIP Compliant (n = 44,064), No. (%)	SCIP Noncompliant (n = 1,240), No. (%)	Total (n = 45,304), No. (%)
General surgery	9,886 (22.5)	165 (13.4)	10,051 (22.3)
Gynecology	1,814 (4.1)	37 (3.0)	1,851 (4.1)
Neurosurgery	6,216 (14.2)	171 (13.9)	6,387 (14.2)
Spine	1,336 (3.0)	13 (1.1)	1,349 (3.0)
Orthopedics	1,801 (4.1)	46 (3.7)	1,847 (4.1)
Otolaryngology	2,692 (6.1)	66 (5.4)	2,758 (6.1)
Plastics	1,990 (4.5)	32 (2.6)	2,022 (4.5)
Pediatric surgery	8,732 (19.9)	334 (27.1)	9,066 (20.1)
Thoracic	1,586 (3.6)	103 (8.4)	1,689 (3.7)
Transplant	1,294 (3.0)	28 (2.3)	1,322 (2.9)
Urology	4,810 (11.0)	126 (10.2)	4,936 (10.9)
Vascular	1,405 (3.2)	105 (8.5)	1,510 (3.4)
Total	43,903 (97.3)	1,231 (2.7)	45,134 (100)

There is a discrepancy between the "n" in the top row and the "Total" in the bottom row, because 161 patients in the SCIP-compliant group and 9 patients in the SCIP-noncompliant group did not have an assigned surgical service.

SCIP = Surgical Care Improvement Project.

whereas the noncompliant group had a greater percentage of pediatric, thoracic, and vascular surgery cases.

Patients in the SCIP-compliant group had a mean body temperature measurement at PACU or ICU admission that was 1.1°C higher than that of patients in the SCIP-noncompliant group ( $P < 0.0001$ ; table 3). Active warming was used in 64.1% of the SCIP-compliant patients, and, by definition of SCIP compliance, none of the SCIP-noncompliant patients had active warming. When forced-air warming was used, 36% of patients had an upper body cover, 41% had a lower body cover, and 22% had both. Duration of surgery was longer in the SCIP-compliant

group (table 3). The percentage of patients receiving an intraoperative blood transfusion was higher in the SCIP-noncompliant group (15.4%) compared with the SCIP-compliant group (9.2%;  $P < 0.0001$ ). At the end of surgery, mean body temperature was similar in the transfused patients ( $36.6^\circ \pm 1.2^\circ\text{C}$ ) and the nontransfused patients ( $36.6^\circ \pm 0.9^\circ\text{C}$ ;  $P = 0.84$ ).

Clinical outcomes were initially compared in the two groups by univariable (nonrisk adjusted) analysis (table 4). The incidence of hospital-acquired infection was lower in the SCIP-compliant group than in the SCIP-noncompliant group (3,312 [7.5%] *vs.* 160 [12.9%] events;  $P < 0.0001$ ). This difference was attributed to a decreased occurrence of *C. difficile*, sepsis, and drug-resistant infections, as postoperative wound infections occurred with similar frequency in the two groups. Ischemic cardiovascular events occurred less frequently in the SCIP-compliant group than in the SCIP-noncompliant group events (602 [1.4%] *vs.* 38 [3.1%] events;  $P < 0.0001$ ). This difference was attributed to a lower frequency of both cerebral (transient ischemic attack or cerebral vascular accident) ischemic events and myocardial infarction. When compared with that in the SCIP-noncompliant group, the SCIP-compliant group exhibited a lower in-hospital mortality rate (617 [1.4%] *vs.* 60 [4.8%] events;  $P < 0.0001$ ) and shorter median (interquartile range) length of stay (4 [2 to 8] *vs.* 5 [2 to 14] days;  $P < 0.0001$ ).

We assessed the same clinical outcomes to determine the independent relationship between SCIP compliance and adverse outcomes using a multivariable analysis to risk adjust for confounding variables (table 5). SCIP compliance was associated with a reduced risk for hospital-acquired infection, ischemic cardiovascular events, and in-hospital mortality. By using the same independent variables as were used for

Table 3. Perioperative Temperature and Thermal Management

	SCIP Compliant (n = 44,064)	SCIP Noncompliant (n = 1,240)	P Value
End operating room temperature (°C)	36.3 ± 0.9	35.1 ± 0.5	<0.0001
10th percentile	34.0	34.0	
25th percentile	35.2	34.4	
50th percentile	36.4	35.2	<0.0001*
75th percentile	37.0	35.6	
90th percentile	37.4	35.8	
PACU/ICU admit temperature (°C)	36.6 ± 0.6	35.5 ± 0.5	<0.0001
10th percentile	36.0	34.9	
25th percentile	36.2	35.4	
50th percentile	36.5	35.7	<0.0001*
75th percentile	36.9	35.8	
90th percentile	37.3	35.9	
Duration of surgery (min)			
Mean ± SD	254 ± 147	224 ± 140	<0.0001
Median (IQR)	220 (147–322)	188 (123–279)	<0.0001
Active warming (% of patients)	64.1	0	<0.0001

\* Comparison of median and percentile distribution temperature measures in the two groups by the Mann-Whitney U test.

ICU = intensive care unit; IQR = interquartile range; PACU = postanesthesia care unit; SCIP = Surgical Care Improvement Project.

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Table 4. Primary and Secondary Outcomes by Univariable Analysis

	SCIP Compliant (n = 44,064), No. (%)	SCIP Noncompliant (n = 1,240), No. (%)	Univariable (Unadjusted) Effect for SCIP Compliance, OR (95% CI)	P Value
Any infection	3,312 (7.5)	160 (12.9)	0.55 (0.44–0.69)	<0.0001
<i>Clostridium difficile</i>	569 (1.3)	31 (2.5)	0.51 (0.32–0.82)	0.0008
Sepsis	1,350 (3.1)	93 (7.5)	0.39 (0.29–0.52)	<0.0001
Wound infection	1,673 (3.8)	44 (3.6)	0.93 (0.63–1.39)	0.7811
Drug-resistant infection	235 (0.5)	16 (1.3)	0.41 (0.21–0.80)	0.0016
Ischemic cardiovascular event	602 (1.4)	38 (3.1)	0.44 (0.28–0.68)	<0.0001
TIA or CVA	446 (1.0)	27 (2.2)	0.46 (0.29–0.72)	0.0005
MI	164 (0.4)	11 (0.9)	0.42 (0.21–0.84)	0.008
In-hospital mortality	617 (1.4)	60 (4.8)	0.28 (0.20–0.40)	<0.0001
Length of stay				
Mean LOS (d)	9.0 ± 19.1	13.6 ± 24.2		<0.0001
Median (IQR) LOS (d)	4 (2–8)	5 (2–14)		<0.0001

ORs and P values are reported after Bonferroni *post hoc* adjustment for multiple comparisons.

CVA = cerebral vascular accident; IQR = interquartile range; LOS = length of stay; MI = myocardial infarction; OR = odds ratio; SCIP = Surgical Care Improvement Project; TIA = transient ischemic attack.

Table 5. Primary and Secondary Outcomes by Multivariable Analysis

	Risk-adjusted Effect for SCIP Compliance, OR (95% CI)	P Value	Risk-adjusted Effect for Temperature ≥36°C, OR (95% CI)	P Value	Risk-adjusted Effect for Active Warming, OR (95% CI)	P Value
Any infection	0.68 (0.54–0.85)	<0.0001	0.76 (0.66–0.88)	<0.0001	0.75 (0.68–0.83)	<0.0001
<i>Clostridium difficile</i>	0.63 (0.40–1.04)	0.021	0.66 (0.49–0.89)	0.0006	0.68 (0.55–0.85)	<0.0001
Sepsis	0.53 (0.40–0.72)	<0.0001	0.65 (0.53–0.80)	<0.0001	0.65 (0.57–0.76)	<0.0001
Wound infection	0.86 (0.56–1.24)	0.31	0.92 (0.75–1.14)	0.33	0.93 (0.82–1.06)	0.16
Drug-resistant infection	0.56 (0.31–1.17)	0.047	0.64 (0.45–0.96)	0.02	0.79 (0.57–1.11)	0.08
Ischemic cardiovascular event	0.60 (0.41–0.92)	0.008	0.57 (0.44–0.74)	<0.0001	0.79 (0.66–0.96)	0.008
TIA or CVA	0.61 (0.39–1.00)	0.026	0.57 (0.43–0.76)	<0.0001	0.78 (0.63–0.98)	0.015
MI	0.67 (0.34–1.52)	0.25	0.77 (0.47–1.13)	0.26	0.86 (0.60–1.25)	0.36
In-hospital mortality	0.41 (0.29–0.58)	<0.0001	0.36 (0.29–0.46)	<0.0001	0.64 (0.53–0.77)	<0.0001

OR and 95% CIs from the multivariable analysis are shown to illustrate the risk-adjusted effects of SCIP compliance, temperature ≥36°C, and active warming, on each of the adverse clinical outcomes. Each of these three parameters was associated with a reduced risk of any infection, ischemic cardiovascular events, and in-hospital mortality. OR and P values are reported after Bonferroni *post hoc* adjustment for multiple comparisons. Patient characteristics included as independent variables in the multivariable models were: Charlson score, congestive heart failure, valvular cardiac disease, peripheral vascular disease, hypertension, pulmonary disease, renal disease, metastatic disease, and obesity.

CVA = cerebral vascular accident; MI = myocardial infarction; OR = odds ratio; SCIP = Surgical Care Improvement Project; TIA = transient ischemic attack.

the outcomes assessment, SCIP compliance was associated with a reduced risk for a length of stay that was greater than the median for all patients (4 days; OR, 0.83; 95% CI, 0.74 to 0.94), in a multivariable analysis.

In subsequent analyses, we used the same multivariable model, except that we substituted the use of “any temperature greater than or equal to 36°C” and then “active warming” for “SCIP compliance” as the primary independent variable (table 5). Both temperature greater than or equal to 36°C and active warming were independently associated with reduced risk of all three adverse outcomes: hospital-acquired infection, ischemic cardiovascular events, and in-hospital mortality. Of note is the finding that the risk of wound infection and myocardial infarction alone (outside the defined composite outcome) were not significantly reduced with SCIP compliance, temperature greater than or equal to 36°C, or active warming.

## Discussion

The primary findings in this study were that SCIP Inf-10 compliance was associated with a reduced risk for hospital-acquired infections, ischemic cardiovascular events, and mortality, as well as a decreased length of stay. These findings suggest that perioperative maintenance of normothermia according to the SCIP Inf-10 guideline is an important process measure that can be used as a perioperative quality measure. Our findings also support those of the original randomized clinical trials by Kurz *et al.*<sup>16</sup> and Frank *et al.*,<sup>17</sup> on which this SCIP measure was based, whereby preventing perioperative hypothermia—reduced infections<sup>16</sup> and ischemic cardiovascular morbidity.<sup>17</sup> An additional benefit of maintaining normothermia is reduced perioperative bleeding and transfusion requirements,<sup>22</sup> which further justifies the importance of this particular SCIP measure.

Although SCIP Inf-10 compliance was associated with reduced morbidity as defined by our primary outcome measures, it should be noted that the effect of SCIP compliance on postoperative wound infection alone was not significant and that the effect on myocardial infarction alone was significant only in the unadjusted analysis and not after risk adjustment. A possible explanation for these findings may be that we included all surgical inpatients in the analysis, and not just those at high risk for these particular morbid events, as was the case in the original clinical trials by Kurz *et al.*<sup>16</sup> and Frank *et al.*<sup>17</sup> It is likely that because the patient population was all-inclusive, we only recognized the reduced morbidity when the composite outcomes were considered. The very low incidence of myocardial infarction in our study is evidence that our population was an overall low-risk group of patients for this particular outcome. In addition, most perioperative myocardial infarctions are silent.<sup>23</sup> We also had a lower risk population for wound infection compared with the randomized trial by Kurz *et al.*,<sup>16</sup> where all patients had colorectal surgery. This may explain why in our study the composite infection outcome was significantly increased but wound infection by itself was not.

In simplified terms, body temperature is an important vital sign, and quality anesthetic care aims to control and maintain vital signs near normal baseline values. The physiologic effects of even mild hypothermia in awake humans have been well described. Intense vasoconstriction occurs as a result of the adrenergic response to core hypothermia,<sup>24</sup> which increases norepinephrine concentrations to 300 to 400% above baseline<sup>25,26</sup> and produces a smaller but substantial increase in epinephrine, about twofold.<sup>25</sup> This normal thermoregulatory response increases vasomotor tone, which reduces heat loss through the skin surface, thus increasing core temperature. The resulting decrease in skin blood flow has detrimental effects on oxygen delivery to the skin surface.<sup>27</sup> This reduction in oxygen may contribute to the increased risk of wound infection, as macrophages may be dysfunctional in hypoxemic tissues,<sup>28</sup> allowing bacteria to take hold in the wound surface. In addition, leukocytes become dysfunctional at lower temperature and have less ability to defend the body against infection.<sup>29</sup> The adrenergic response to hypothermia has also been implicated as the mechanism for cold-induced perioperative myocardial ischemia.<sup>17</sup>

The SCIP measures have been criticized in the literature primarily because they are process measures used as a surrogate for quality measures.<sup>1,2</sup> Furthermore, and with few exceptions, SCIP-measure compliance has been shown by previous investigators to be poorly correlated with clinical outcomes.<sup>8–14</sup> For hospital-acquired infections, Ingraham *et al.*<sup>10</sup> analyzed data from 200 hospitals and showed that giving antibiotics within 60 min of incision (SCIP Inf-1), discontinuing the antibiotic within 24 h after surgery (SCIP Inf-3), and appropriate hair removal from the surgical site (SCIP Inf-6) were all unrelated to the incidence of surgical site infection (SSI), even in a risk-adjusted analysis. Only the selection of the appropriate antibiotic (SCIP Inf-2) was a

predictor of improved outcome. Maintaining normothermia was not assessed in that particular study.

Other poor correlations between SCIP compliance and outcomes have been reported. Nicholas *et al.*<sup>14</sup> assessed data from 2,000 U.S. hospitals and found that compliance did not correlate with reduced mortality, venous thrombosis rates, or SSI rates, even after risk adjustment. These authors focused on antibiotic start and stop times (SCIP Inf-1 and SCIP Inf-3), antibiotic choice (SCIP Inf-2), and venous thrombosis prophylaxis (SCIP VTE-1 and SCIP VTE-2) measures, but did not assess SCIP-10 because when the data were collected, SCIP-10 had not yet been added to the list of core measures. Recently, Tillman *et al.*<sup>9</sup> reported a before and after comparison study in which SCIP Inf-1 (antibiotic timing), SCIP Inf-2 (antibiotic selection), and SCIP Inf-10 (perioperative temperature management) were all implemented in 2010. Overall, they found no decrease in SSI rate (3.13% before *vs.* 2.96% after,  $P = 0.72$ ). However, they did show a decrease in SSI for the colorectal subgroup (24.1% before *vs.* 11.5% after,  $P = 0.03$ ). This finding suggests that in high-risk patients, the combination of SCIP measures is beneficial. These results are of interest because the original study by Kurz *et al.*<sup>16</sup> was performed in patients undergoing colorectal surgery and provided the evidence on which SCIP Inf-10 is based. Recently, Rasouli *et al.*<sup>8</sup> reported that implementing the entire group of SCIP measures in total joint arthroplasty patients was associated with an *increase* in rate of both superficial SSI and pulmonary embolus, but no change in venous thrombosis or deep SSI. These authors also did not describe specific compliance rates with SCIP-10.

In the 1990s, Sessler<sup>30</sup> conducted a large number of studies showing that virtually all anesthetic drugs and techniques render patients poikilothermic, whereby their body temperature drifts rapidly downward toward ambient temperature. This thermoregulatory impairment is likely due to both central and peripheral mechanisms. The anterior hypothalamus is the body's central "thermostat," but this function is blocked by general anesthetics. Peripheral cold defense mechanisms such as vasoconstriction and shivering are also impaired by general and neuraxial (spinal and epidural) anesthetic techniques.<sup>24,31</sup> In fact, all these anesthetic methods are associated with the development of intraoperative hypothermia.<sup>24</sup>

The advent of forced-air warming in the late 1980s was a true breakthrough in perioperative care. Studies have shown this to be the most effective method of maintaining normothermia.<sup>32</sup> Forced-air warming was used in virtually all patients who received active warming in this study. Considering the current cost of the forced-air "cover" (blanket) at approximately \$6 USD, this may one of the simplest, most cost-effective methods of improving perioperative care. Given our current findings and the "quality-over-cost-equals-value" equation, forced-air warming is clearly a high-value method for improving perioperative care.

Limitations in this study may include the following. Some baseline preoperative patient characteristics differed between

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groups, as is commonly seen in retrospective outcome studies addressing an intervention. These differences were only recognized for specific comorbidities, and we believe that we evaluated clinical outcomes in a risk-adjusted fashion in the multivariable analysis. Furthermore, we included a propensity score to further adjust for confounding variables. The risk adjustment also included duration of surgery, requirement for blood transfusions, and year of surgery, all of which could conceivably be related to adverse outcomes. Like other administrative database studies, we used ICD-9 codes from the hospital's billing database to assess morbid outcomes. This method may be less reliable than prospectively recorded outcomes.<sup>33</sup> However, the method we used offers less chance for investigator bias in determining morbidity. Another potential limitation is the reliance on "hand-entered" data, for example, to document the use of active warming. It was surprising that only 64% of the SCIP compliant group was noted to be actively warmed, and it is likely that this percentage would be higher if the electronic record was 100% reliable. Finally, we recognize that the body temperature we measured on admission to the PACU or ICU may not represent a true core temperature. The temporal artery infrared thermometer that was used is known to be a somewhat unreliable indicator of true core temperature, with some studies supporting and some refuting its use as a core temperature monitor.<sup>34–36</sup> However, using a truly accurate core temperature measurement site (e.g., distal esophagus) is not feasible in awake postoperative patients. Thus, temporal artery thermometry is typically used in many hospitals to satisfy the definition of SCIP compliance, which states that "body temperature," not true core temperature, should be greater than or equal to 36°C. We also recognize a limitation with reporting body temperature within the last 30 min of surgery, as it was not uncommon for the temperature probe to be removed from the patient near the end of the surgical procedure, thus rendering a missing value. This practice is also a "routine care" and representative of what is typically available for SCIP measure reporting. However, there were many fewer missing temperature measurements on admission to the PACU/ICU.

In conclusion, our findings show that compliance with the SCIP Inf-10 measure was associated with a reduced incidence of hospital-acquired infections, ischemic cardiovascular events, and mortality, as well as a reduced length of stay. Our findings support those from previous randomized trials showing improved outcomes when perioperative hypothermia is prevented. Furthermore, our results suggest that the process measure defined by SCIP Inf-10 can and should be used as a valid measure of perioperative care quality. Because active patient warming is an inexpensive perioperative intervention that can improve outcome, it is a high-value method of improving care.

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### Competing Interests

The authors declare no competing interests.

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## PERIOPERATIVE MEDICINE

## Appendix: ICD-9 Codes Used to Define Clinical Outcomes

Infection/Complication	ICD-9 Code	Diagnosis Description
C Diff	008.45	<i>Clostridium difficile</i>
Cerebral vascular accident	434.01	Cerebral Thrombosis W/Ci
Cerebral vascular accident	434.11	Cerebral Embolism W Ci
Cerebral vascular accident	434.91	Cerebral Artery Occlusion, Unspecified W/Ci
Cerebral vascular accident	997.02	Iatrogenic Cv Infarction
Drug-resistant antibiotic infection	V09.0	Penicillin Resistant Infection
Drug-resistant antibiotic infection	V09.1	Cephalosporin Resistant Infection
Drug-resistant antibiotic infection	V09.2	Macrolides Resistant Infection
Drug-resistant antibiotic infection	V09.3	Tetracyclines Resistant Infection
Drug-resistant antibiotic infection	V09.4	Aminoglycosides Resistant Infection
Drug-resistant antibiotic infection	V09.50	Quinolones/Fluoroq Resistant Infection
Drug-resistant antibiotic infection	V09.51	Quinolones/Fluoro Resistant Infection
Drug-resistant antibiotic infection	V09.6	Sulfonamides Resistant Infection
Drug-resistant antibiotic infection	V09.70	Antimycobacterial Resistant Infection
Drug-resistant antibiotic infection	V09.71	Other Antimycobacterial Resistant Infection
Drug-resistant antibiotic infection	V09.80	Spec Drug Resistant Infection
Drug-resistant antibiotic infection	V09.81	Multiple Drug Resistant Infection
Drug-resistant antibiotic infection	V09.90	Drug-Resistant Microorganism
Drug-resistant antibiotic infection	V09.91	Multiple Drug-Resistant Microorganism
Myocardial infarction	410.00	Ami A/L Wall/Unspecified Episode
Myocardial infarction	410.01	Ami A/L Wall/1st Episode
Myocardial infarction	410.02	Ami A/L Wall/Subsequent Episode
Myocardial infarction	410.10	Ami Ant Wall/Unspecified Episode
Myocardial infarction	410.11	Ami Ant Wall/1st Episode
Myocardial infarction	410.12	Ami Ant Wall/Subsequent Episode
Myocardial infarction	410.20	Ami I/L Wall/Unspecified Episode
Myocardial infarction	410.21	Ami I/L Wall/1st Episode
Myocardial infarction	410.22	Ami I/L Wall/Subsequent Episode
Myocardial infarction	410.30	Ami I/P Wall/Unspecified Episode
Myocardial infarction	410.31	Ami I/P Wall/1st Episode
Myocardial infarction	410.32	Ami I/P Wall/Subsequent Episode
Myocardial infarction	410.40	Ami Inf Wall/Unspecified Episode
Myocardial infarction	410.41	Ami Inf Wall/1st Episode
Myocardial infarction	410.42	Ami Inf Wall/Subsequent Episode
Myocardial infarction	410.50	Ami Other Wall/Unspecified Episode
Myocardial infarction	410.51	Ami Lat Wall/1st Episode
Myocardial infarction	410.52	Ami Lat Wall/Subsequent Episode
Myocardial infarction	410.60	Ami Pos Wall/Unspecified Episode
Myocardial infarction	410.61	Ami Pos Wall/1st Episode
Myocardial infarction	410.62	Ami Pos Wall/Subsequent Episode
Myocardial infarction	410.70	Subendocardial Ami/Unspecified Episode
Myocardial infarction	410.71	Subendocardial Ami/1st Episode
Myocardial infarction	410.72	Subendocardial Ami/Subsequent Episode
Myocardial infarction	410.80	Ami Other Site/Unspecified Episode
Myocardial infarction	410.81	Ami Other Site/1st Episode
Myocardial infarction	410.82	Ami Other Site/Subsequent Episode
Myocardial infarction	410.90	Ami Unspecified/Unspecified Episode
Myocardial infarction	410.91	Ami/Unspecified Site/1st Episode
Myocardial infarction	410.92	Ami/Unspecified Site/Subsequent Episode
Postoperative wound infection	998.51	Infected Postoperative Seroma
Postoperative wound infection	998.59	Other Postoperative Infection
Sepsis	038.9	Septicemia Nos
Sepsis	670.20	Puerperal Sepsis - Unspecified as to Episode of Care or Not Applicable
Sepsis	670.22	Puerperal Sepsis, Delivered, with Mention of Postpartum Complication

(Continued)

**Appendix. Continued**

Infection/Complication	ICD-9 Code	Diagnosis Description
Sepsis	670.24	Puerperal Sepsis—Postpartum Condition or Complication
Sepsis	771.81	Newborn Septicemia
Sepsis	995.91	Sepsis
Transient ischemic attack	435.0	Basilar Artery Syndrome
Transient ischemic attack	435.1	Vertebral Artery Syndrome
Transient ischemic attack	435.2	Subclavian Steal Syndrome
Transient ischemic attack	435.3	Vertebrobasilar Artery Syndrome
Transient ischemic attack	435.8	Transient Cerebral Ischemia Nec
Transient ischemic attack	435.9	Transient Cerebral Ischemia Nos

A/L = anterolateral; Ami = acute myocardial infarction; Ant = anterior; Ci = cerebral infarction; ICD-9 = *International Classification of Diseases*, ninth Revision; IL = inferolateral; I/P = inferoposterior; Lat = lateral; Nec = not elsewhere classified; Nos = not otherwise specified.

# Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients

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**BACKGROUND:** Several adverse consequences are caused by mild perioperative hypothermia. Maintaining normothermia with patient warming systems, today mostly with forced air (FA), has thus become a standard procedure during anesthesia. Recently, a polymer-based resistive patient warming system was developed. We compared the efficacy of a widely distributed FA system with the resistive-polymer (RP) system in a prospective, randomized clinical study.

**METHODS:** Eighty patients scheduled for orthopedic surgery were randomized to either FA warming (Bair Hugger warming blanket #522 and blower #750, Arizant, Eden Prairie, MN) or RP warming (Hot Dog Multi-Position Blanket and Hot Dog controller, Augustine Biomedical, Eden Prairie, MN). Core temperature, skin temperature (head, upper and lower arm, chest, abdomen, back, thigh, and calf), and room temperature (general and near the patient) were recorded continuously.

**RESULTS:** After an initial decrease, core temperatures increased in both groups at comparable rates (FA:  $0.33^{\circ}\text{C}/\text{h} \pm 0.34^{\circ}\text{C}/\text{h}$ ; RP:  $0.29^{\circ}\text{C}/\text{h} \pm 0.35^{\circ}\text{C}/\text{h}$ ;  $P = 0.6$ ). There was also no difference in the course of mean skin and mean body (core) temperature. FA warming increased the environment close to the patient (the workplace of anesthesiologists and surgeons) more than RP warming ( $24.4^{\circ}\text{C} \pm 5.2^{\circ}\text{C}$  for FA vs  $22.6^{\circ}\text{C} \pm 1.9^{\circ}\text{C}$  for RP at 30 minutes;  $P_{\text{AUC}} < 0.01$ ).

**CONCLUSION:** RP warming performed as efficiently as FA warming in patients undergoing orthopedic surgery. (Anesth Analg 2010;110:834–8)

Perioperative hypothermia is a common problem challenging the anesthesiologist. It is caused by the inhibition of thermoregulation induced by anesthesia, redistribution of body heat from the core to the periphery, and the exposure of the patient's skin and tissues to a cold environment in the operating room (OR).<sup>1</sup> Even mild hypothermia triples the incidence of postoperative wound infection and increases the hospital length of stay by 20%,<sup>2</sup> increases blood loss and blood transfusion requirements,<sup>3</sup> and increases the incidence of cardiovascular complications<sup>4</sup> and the thermal discomfort of patients.<sup>5</sup> Consequently, intraoperative active warming has become a standard procedure during general anesthesia. Forced-air (FA) warming, the most common approach, is relatively inexpensive, safe, easily performed, and has proven to be highly effective.<sup>6–9</sup>

Recently, a new warming system (Hot Dog, Augustine Biomedical, Eden Prairie, MN) was introduced that uses a different, conductive warming technology: an electric current heats a resistive-polymer (RP) blanket. This system might have some advantages compared with an FA warming system: blankets are reusable, there is no air flow and thus warming can be initiated immediately after induction of anesthesia without waiting for surgical draping to be

completed, and its operation is silent. However, the principle of electric blanket warming is based primarily on conductive warming and therefore requires direct skin contact to work effectively. In contrast, FA systems work with redundant amounts of warm air, which also flow around large areas of the patient's skin not covered by the actual blanket; thus, a close contact between the FA blanket and the patient's skin is not required. This difference in the mechanisms of action partly explains the heterogeneous results of previous studies comparing resistive versus FA warming devices. Some authors have shown comparable warming efficacy of these 2 technologies.<sup>10–13</sup> Other authors have found the efficacy of resistive warming blankets to be inferior.<sup>14,15</sup> In these studies, carbon-fiber systems were primarily evaluated.

Recently, Kimberger et al.<sup>16</sup> published a crossover study comparing the Hot Dog RP warming system with a FA device and showed comparable heat transfer and rewarming rates in volunteers. In this study, we compared the Hot Dog RP warming system device with an FA warming system (Bair Hugger, Arizant, MN) in a randomized, controlled manner in surgical patients.

## METHODS

With approval of the IRB of the Medical University of Vienna and written informed consent obtained on the day before surgery, we studied 80 patients undergoing elective orthopedic surgery with general or combined general-regional anesthesia. Before patient enrollment, this study was registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under number NCT00772460. The only exclusion criterion was severe peripheral artery disease in the warmed extremity because FA patient warming is routinely used for all patients during these procedures.

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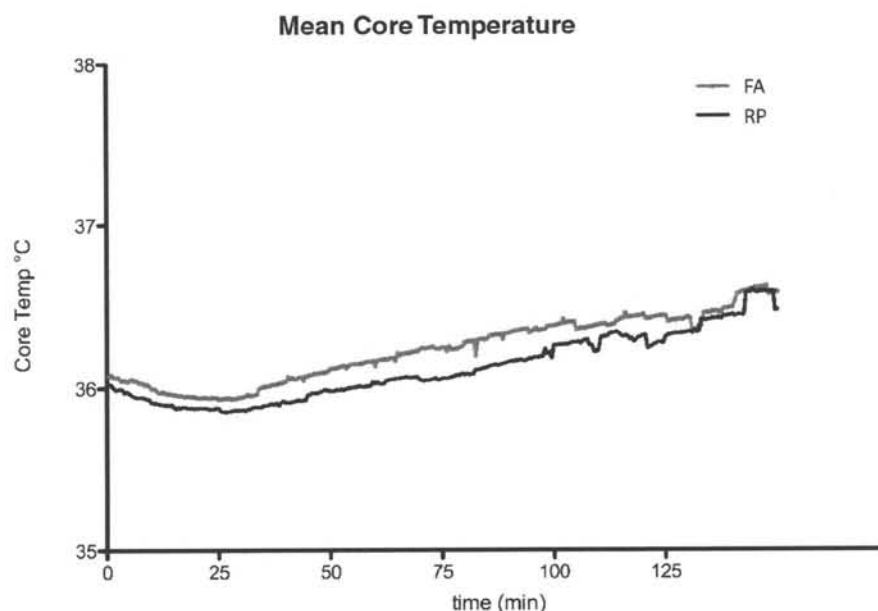
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**Figure 1.** Mean core temperature (0 minute represents induction of anesthesia). Gray: forced air (FA) ( $n = 40$ ); black: resistive polymer (RP) ( $n = 40$ ).



Before induction of anesthesia, patients were randomly assigned, using a computer-generated randomization sequence in which the group assignment was kept in sequentially numbered, opaque envelopes, to 1 of 2 treatments: (1) FA warming (FA group) with a Bair Hugger upper body warming cover (model #522), connected to a model #750 warming unit set to "high" (43°C); or (2) RP warming (RP group) with 2 Hot Dog warming blankets (model: Multi-Position Blanket) and the Hot Dog controller unit set to "high" (43°C).

As recommended by the manufacturer, we used 2 Hot Dog Multi-Position Blankets, each approximately half the size of a typical upper body FA blanket. For upper body warming, straps connected the 2 Hot Dog blankets, resulting in 1 normal-size upper body blanket. Anesthetic, hemodynamic, and fluid management were at the discretion of the attending anesthesiologist. General anesthesia was provided with inhaled sevoflurane in oxygen and IV fentanyl as per departmental routine. Combined regional-general anesthesia consisted of general anesthesia in combination with femoral nerve block, and in all cases of regional anesthesia, spinal anesthesia was performed.

### Measurements

Before induction of anesthesia, skin temperature probes (Mon-a-therm, Mallinckrodt Anesthesiology Products, St. Louis, MO) were attached to the patient's head, upper and lower arm, chest, abdomen, back, thigh, and calf. Mean body temperature was calculated using the Burton formula<sup>17</sup>:

$$\text{Mean body temperature} = 0.64 \times T_{\text{core}} + 0.36 \times T_{\text{skin}}$$

Mean skin temperature was calculated using a simplified formula based on body surface area:

$$0.06 \times T_{\text{head}} + 0.09 \times T_{\text{arm}} + 0.06 \times T_{\text{forearm}} + 0.19 \times T_{\text{back}} + 0.095 \times T_{\text{chest}} + 0.095 \times T_{\text{abdomen}} + 0.19 \times T_{\text{thigh}} + 0.115 \times T_{\text{calf}}$$

The core warming rate (°C/h) was calculated from a starting point 30 minutes after induction of anesthesia to the end of surgery, because the typical initial core temperature decrease reaches its maximum at this time (because of blood redistribution), and rewarming starts (Fig. 1).

After induction of anesthesia, a temperature probe (Smiths-Medical, London, UK) was inserted into the distal esophagus (in patients receiving general or combined anesthesia) or into the urinary bladder (in patients receiving regional anesthesia) to measure core body temperature; subsequently, warming with the randomized warming device was started. All temperature measurements were recorded every 5 minutes until the end of surgery. Additionally, we recorded demographic and morphometric variables (gender, age, and body mass index), the duration of surgery, type of anesthesia, IV infusions and blood loss, vasopressor therapy, and environmental temperature close to the patient (approximately 1 m distance) and in the OR. Thirty minutes after arrival in the postoperative care unit, the patient's individual thermal comfort was evaluated with a visual analog scale (VAS) (0 = extreme cold, 100 = extreme heat, and 50 = thermoneutrality). The necessity of postoperative warming was recorded, using the threshold for postoperative active warming of our institution (core temperature <35°C at the time of planned tracheal extubation).

### Statistical Analysis

To calculate sample size, a power analysis for equivalence (unpaired test) was performed. Lower and upper equivalence bounds were  $\pm 0.5^\circ\text{C}$  core temperature, with an SD of  $0.6^\circ\text{C}$  calculated from previous data. A total sample size of 80 patients was estimated to achieve a power of 90% to detect equivalence within the specified equivalence bounds. For the analysis of core and mean body temperature, we calculated the area under the temperature curves (AUCs), normalized for duration of surgery. Differences for

**Table 1. Demographic, Anesthesiological, and Temperature Data**

Parameter	BairHugger (FA) forced-air warming	HotDog (RP) resistive polymer warming	
Age (y)	39 ± 16	37 ± 13	<i>P</i> = NS
Gender (male/female)	16/24	31/9	<i>P</i> < 0.01
Body mass index (BMI; kg/m <sup>2</sup> )	25.5 ± 4.0	25.6 ± 3.4	<i>P</i> = NS
Anesthesia (general/regional/combined)	32/3/3	32/4/3	<i>P</i> = NS
Duration of surgery (min)	91 ± 41	83 ± 40	<i>P</i> = NS
Duration of anesthesia (min)	110 ± 43	95 ± 41	<i>P</i> = NS
Blood loss (mL)	54 ± 54	38 ± 44	<i>P</i> = NS
Sevoflurane (end-tidal vol%)	2.0 ± 0.7	1.9 ± 1.1	<i>P</i> = NS
Fentanyl (μg · kg <sup>-1</sup> · h <sup>-1</sup> )	1.6 ± 0.8	1.7 ± 0.7	<i>P</i> = NS
Infusion (mL)	1243 ± 500	1180 ± 469	<i>P</i> = NS
OR temperature start (°C)	19.5 ± 0.4	19.5 ± 0.5	<i>P</i> = NS
OR temperature end (°C)	19.4 ± 0.6	19.5 ± 0.5	<i>P</i> = NS
Environmental temperature (°C) at 1 m distance to warming device (after 30 min)	24.4 ± 5.2	22.6 ± 1.9	AUC: <i>P</i> < 0.01
Core temperature start (°C)	36.1 ± 0.5	36.0 ± 0.4	<i>P</i> = NS
Core temperature end (°C)	36.4 ± 0.5	36.2 ± 0.4	<i>P</i> = NS
Slope of core temperature curve (after 30 min to end °C per hour)	0.33 ± 0.34	0.29 ± 0.35	<i>P</i> = NS
Mean body temperature start (°C)	34.7 ± 0.6	34.8 ± 0.4	AUC: <i>P</i> = NS
Mean body temperature end (°C)	35.9 ± 0.5	36.4 ± 0.3	AUC: <i>P</i> = NS
Mean skin temperature start (°C)	32.2 ± 1.2	32.5 ± 0.9	AUC: <i>P</i> = NS
Mean skin temperature end (°C)	34.6 ± 1.3	35.8 ± 1.14	AUC: <i>P</i> = NS
Thermal comfort VAS (0–100)	51 ± 6	56 ± 11	<i>P</i> = NS

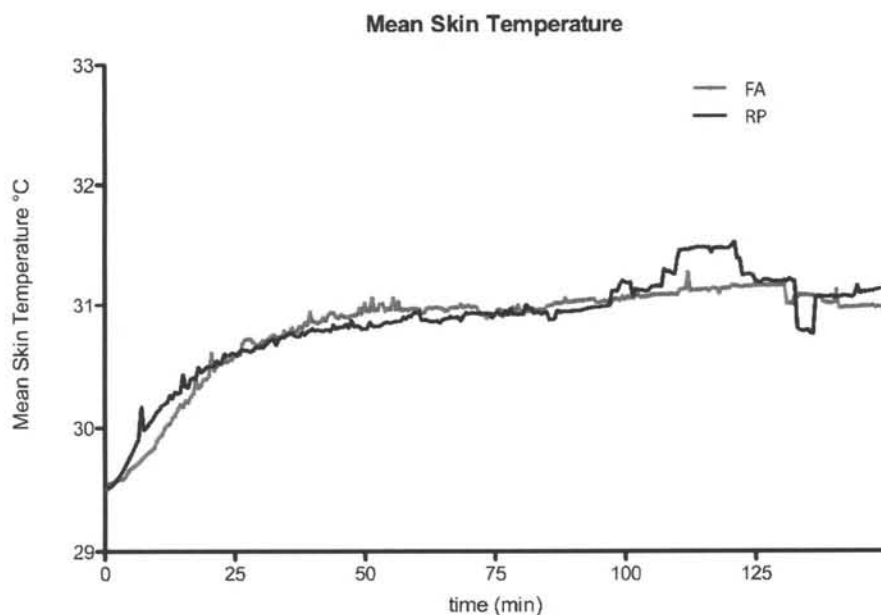
AUC = area under parameter curve (normalized for operation duration); VAS = visual analog scale; OR = operating room.

demographic and morphometric variables between the RP and FA groups were calculated with unpaired Student *t* test, distribution of gender was calculated with Fisher exact test, and distribution of anesthesia method with  $\chi^2$  test. Results are expressed as means ± SD. Differences were considered statistically significant at *P* < 0.05.

## RESULTS

Eighty patients were assigned to either the FA (*n* = 40) or the RP group (*n* = 40) and treated as intended by protocol. There were no differences in demographic and morphometric characteristics (Table 1), except for gender with more female patients in the FA group.

After induction of anesthesia, core temperature decreased similarly for a period of approximately 30 minutes in both groups (Fig. 1). Subsequently, core temperature increased at comparable rates in both groups (0.33 °C/h ± 0.34 °C/h and 0.29 °C/h ± 0.35 °C/h for groups FA and RP, respectively; *P* = 0.6). There were also no differences between the 2 groups in the course of core temperature (Fig. 1, Table 1; *P* = 0.12), mean body temperature (Table 1; *P* = 0.11), and mean skin temperature (Fig. 2, Table 1; *P* = 0.48; all *P* values for comparison of normalized AUCs). We did not find significant intragroup core temperature differences between patients with esophageal and bladder core temperature probes (results not shown).



**Figure 2.** Mean skin temperature (0 minute represents induction of anesthesia). Gray: forced air (FA) (*n* = 40); black: resistive polymer (RP) (*n* = 40).

There were no differences in end-tidal sevoflurane concentrations or administered fentanyl between the 2 groups (Table 1). No patient in this study needed postoperative warming in the recovery room. Thirty minutes after admission to the postanesthesia recovery room, the patients' thermal comfort (evaluated using the VAS) was not different between the FA (VAS  $51 \pm 6$ ) and RP (VAS  $56 \pm 11$ ,  $P = 0.09$ ) groups.

There were no heat-induced injuries or other device-associated complications in any of the patients. Maximal skin temperature was  $39.2^{\circ}\text{C}$  (chest) in 1 patient in the FA group and  $39.3^{\circ}\text{C}$  (abdomen) in 1 patient in the RP group. The room temperature and the environmental temperature (close proximity to the patient) were not different at induction of anesthesia between the FA and the RP groups. In contrast, the environmental temperature in close proximity to the workplace of the surgical and anesthesia team increased more with the FA patient warmer ( $24.4^{\circ}\text{C} \pm 5.2^{\circ}\text{C}$  for FA vs  $22.6^{\circ}\text{C} \pm 1.9^{\circ}\text{C}$  for RP at 30 minutes,  $P_{\text{AUC}} < 0.01$ ; Table 1).

## DISCUSSION

Induction of anesthesia leads to a temperature redistribution from core to periphery, which is difficult to prevent with passive methods (e.g., insulation),<sup>18,19</sup> thus almost every patient is dependent on active warming to prevent accidental perioperative hypothermia. FA warming represents a quasi-standard for perioperative thermal management because of its high efficacy and safety.<sup>6–9,20,21</sup> Efficacy is defined by blower strength, air temperature, and the covered skin area.<sup>21,22</sup> However, blower strength is limited by fan noise and energy consumption, the covered skin surface is limited by the dimensions of the surgical field, and the air temperature is limited by the heat tolerance of the human skin. Thus, the highest allowed setting for air temperature on most heating devices is  $43^{\circ}\text{C}$ . The danger of thermal injury is highest in compressed, poorly perfused lower parts of the body; however, FA devices warm primarily the uncompressed, well-perfused upper parts. Consequently, FA warming has proved to be safe as long as it is applied correctly.<sup>6–8</sup> Some intrinsic limitations of FA warmers include the expense of using disposable blankets for each patient; the noise of the fan; and the increased OR temperature in the proximity of the device, resulting in thermal discomfort of the surgical staff. Other concerns include potential contamination of the parts of the FA device (e.g., hose and blower) with bacterial pathogens,<sup>23</sup> which could be transferred by the airstream to the surgical field and cause infections.<sup>24</sup> However, several studies challenged the clinical relevance of these results and found no differences in bacterial dispersion with or without FA.<sup>25,26</sup>

The new warming device (Hot Dog) uses a different technology: resistive warming of a polymer blanket. Potential advantages of resistive warming compared with FA warming include the following: all parts of the system are reusable, thereby reducing costs and the environmental burden; there are no moving parts, thus the system is very quiet; there is possibly less warming of the OR environment, resulting in increased thermal comfort for OR staff; and cleaning and disinfection are relatively easy, thus decreasing the risk of colonization with pathogens. There

are, however, some disadvantages of the RP system. First, the blanket is stiffer and tends to wrinkle, which may reduce the surface area in contact with the patient's skin, thus reducing its effectiveness. Because there is no stream of warm air, the efficacy of the system, similar to all resistive-warming systems, is dependent on close skin contact, and the blanket has to be placed on the patient correctly. Incorrect placement may explain the observed tendency of the rewarming curve in the FA group to be steeper and the final mean core temperature in the RP group to be lower. Therefore, the results of our study should be extrapolated with care to settings in which the risk of severe intraoperative hypothermia is high, or those in which hypothermic patients must be warmed quickly from very low core temperatures. Another limitation is that the RP blanket has to be cleaned between cases, thus requiring manpower and cleaning equipment to avoid contamination with pathogens.

Our study demonstrates that intraoperative warming with the RP system was as effective as warming with the FA system. This is concordant to results in volunteers in which comparable heat transfer and core rewarming rates with RP and FA were found.<sup>16</sup> Several previous studies already showed that (carbon-fiber) resistive warming is as effective as FA warming. Negishi et al.<sup>12</sup> showed in a study of 24 patients undergoing major abdominal surgery that resistive warming with a carbon-fiber blanket was as effective as FA warming. More recently, Fanelli et al.<sup>10</sup> demonstrated comparable efficacy of a carbon-fiber resistive-warming blanket versus FA warming in 56 patients undergoing hip replacement.

In contrast, Russell and Freeman<sup>14</sup> found the resistive heating pad system inferior to FA warming with an underbody blanket in 60 patients undergoing liver transplantation. The limitation of this study was that different temperature settings were accepted (maximum for heating pad system was  $39^{\circ}\text{C}$  vs  $48^{\circ}\text{C}$  for FA warming). Leung et al.<sup>15</sup> studied 60 patients undergoing open abdominal surgery and compared a posterior resistive heating pad system with an FA warming system. They found significantly lower efficiency in the resistive heating pad group, with many patients remaining hypothermic at the end of surgery. Notwithstanding, as mentioned earlier, posterior patient-warming systems do have the inherent disadvantage that warming the back of the patient in the supine position is suboptimal because of low perfusion in this area and the danger of pressure-heat injuries.<sup>27</sup> In our study, the maximal skin temperature recorded with RP was  $39.3^{\circ}\text{C}$  compared with  $39.2^{\circ}\text{C}$  with FA. In the absence of ischemia or pressure, these values should be safe. This presumed safety is supported by the lack of heat-induced skin redness or injuries in any of our patients in either group.

There was also no difference in thermal comfort after anesthesia; active warming in the postoperative care unit because of hypothermia was not necessary in any patient in either group.

Interestingly, the OR temperature close to the patient increased significantly at 30 minutes, corresponding to the end of surgery in the first FA group patient. Although this may have resulted in decreased OR staff members' comfort, we did not measure their thermal comfort levels in this study.

This study has several limitations. Two different anatomic locations were used to measure core temperature (esophageal during general and combined general-regional anesthesia, and urinary bladder during regional anesthesia). These methods are both viable methods for core temperature measurements but are not completely interchangeable.<sup>28</sup> However, in this study, we found no significant temperature differences between regional anesthesia patients with bladder thermometry and general anesthesia patients with esophageal thermometry. Patients undergoing very long, open surgery with potential large fluid shifts are at highest risk for perioperative hypothermia. In our study, the mean duration of surgery was 90 minutes, and the typical surgery was limited to the extremities without open abdomen and without massive fluid shifts. This limitation of our study may reduce the applicability of our results to settings in which the risk of hypothermia is greater (prolonged open abdominal and trauma surgery).

In conclusion, RP warming was as effective as FA warming and may be considered an appropriate method for the prevention of accidental perioperative hypothermia. ■■

#### STUDY FUNDING

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#### DISCLOSURE

Ruken Oguz's research fellow salary was partly paid by Augustine Biomedical Products, Eden Prairie, MN. The sponsors were not involved in data analysis or manuscript preparation.

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